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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/569,714	09/21/2006	Elisabeth Meyer	930008-2207	5929

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EXAMINER	
CHEN, CATHERYNE	
ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/569,714	MEYER ET AL.	
	Examiner	Art Unit	
	CATHERYNE CHEN	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6 and 12-29* is/are pending in the application.

4a) Of the above claim(s) *6,28 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5, and 12-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Currently, Claims 1-3, 5-6, 12-29 are pending. Claims 6 and 28-29 are examined on the merits.

In view of the Appeal Brief filed on Oct. 25, 2010, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

Response to Arguments

Applicant's arguments, filed Oct. 25, 2010, with respect to the rejection(s) of claim(s) 1-3, 5 and 12-14 under 35 U.S.C. 103(a) as being unpatentable over Kleinsorgen et al. (US 6165499), Claims 1-3, 5, and 12-27 rejected under 35 U.S.C. 103(a) as being unpatentable over Kleinsorgen et al. (US 6165499) and Fischer et al. (US 6455066 B1) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the following.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 5 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kleinsorgen et al. (US 6165499) in view of Jordan (US 2003/0064093 A1).

Kleinsorgen et al. teaches a transdermal therapeutic system for the controlled release of active substances to human skin (column 1, lines 10-12), where a matrix system consists of a backing layer which is impermeable to active substances and auxiliaries and averted from the skin and an adhesive layer wherein active substance is distributed (column 1, lines 48-51). Components include any conventional adhesive known to the skilled artisan in the form of patches (column 4, lines 62-64). Thus, a matrix type patch is taught. The substrate may be peeled off the film layer, with the film layer remaining on the site of application (column 4, lines 25-28). The film forming polymers include styrene-butadiene-styrene-isoprene copolymers (column 4, lines 39-40, 54-55). The active substances serve to treat diseases (column 5, lines 23-25). Thus, application to skin of a person in need thereof is taught. Transdermal applicable active ingredients include opioid substances such as buprenorphine (column 5, lines 44-45, 67). Aloe vera can be used to care for exhausted and damaged skin (column 6, lines 34-35, 37-38).

However, Kleinsorgen et al. does not teach all the claimed components together.

Jordan teaches transdermal delivery system with skin penetration enhancing vehicle mixed with an aqueous adjuvant from Aloe vera [0006]. Adjuvant will increase the skin penetrating effect by delivering high molecular weight agents [0017].

It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Sussman,* 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943); *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). *In re Kerkhoven*, 626 F. 2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose).

> The reason or motivation to modify a reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. While there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention.
> MPEP 2144 Sources of Rationale Supporting a Rejection Under 35 U.S.C. 103. <http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2144.htm>

The reference does teach that each of the claimed ingredients is suitable for combination in a pharmaceutical composition. Thus, an artisan of ordinary skill would be reasonably expected that the claimed ingredient could be combined together to produce a single pharmaceutical product. This reasonable expectation of success would motivate the artisan to combine the claimed ingredients together into a single composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use aloe with opioid because Jordan teaches transdermal delivery system with an aqueous adjuvant from Aloe vera [0006]. Adjuvant will increase the skin penetrating effect of opioid. One would have been motivated to make transdermal system with aloe for the expected benefit of increasing transdermal delivery of opioid. Absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

Claims 1-3, 5, and 12-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kleinsorgen et al. (US 6165499) and Jordan (US 2003/0064093 A1) as applied to claims 1-3, 5, 12-14, 28-29 above, and further in view of Fischer et al. (US 6455066 B1).

The teachings of Kleinsorgen et al. and Jordan are set forth above and applied as before.

The combination of Kleinsorgen et al. and Jordan do not specifically teach the soybean oil, polyolefin, polyester, polyolefin oil, foil with thickness of 0.5 to 1.5 and especially 0.6 to 1.0 mm, penetrating agent N-methyl pyrrolidone, organic acid.

Fischer et al. teaches dermal drug for formulations and penetrating agents for transdermal administration with vegetable oil, such as soybean oil (column 2, lines 11-12). A patch comprising a pressure sensitive adhesive comprising pharmaceutically acceptable salt and soybean oil (Claim 1), with aloe vera (Claim 2), backing is

polyolefin, polyester, (Claim 4), polyolefin foil (Claim 5), with thickness of from about 0.6 mm to about 1.0 mm (Claim 6). Local anesthetic can be acetylsalicylic acid as an organic acid, buprenorphine and pharmaceutically acceptable salts thereof (column 5, lines 41-42, 44-46, 60-61). Penetration agents of N-methyl pyrrolidone (column 7, lines 9, 14). Suitable preservatives include organic acids (column 6, lines 61-62).

It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Sussman,* 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943); *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). *In re Kerkhoven*, 626 F. 2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose).

> The reason or motivation to modify a reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. While there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention.
>
> MPEP 2144 Sources of Rationale Supporting a Rejection Under 35 U.S.C. 103. <http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2144.htm>

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a patch with soybean oil, polyolefin, polyester, polyolefin oil, foil with thickness of 0.5 to 1.5 and especially 0.6 to 1.0 mm, penetrating agent N-methyl pyrrolidone, organic acid because these are components are used in a patch for application to skin. One would have been motivated to make a patch for skin for the expected benefit of increasing skin penetration and effective application on a patch formulation as taught by Fischer et al. Absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use preservatives in transdermal analgesics because preservatives such as organic acids can be used to prevent spoilage of drugs. One would have been motivated to make formulation for patch for the expected benefit of preventing spoilage of the drugs. Absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Examiner Art Unit 1655

/Michele Flood/

Primary Examiner, Art Unit 1655